II. Safety and Effectiveness Summary

A. Contact Information

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B. Device Name

Micrus Modified MicroCoil System, "Cerecyte"

Device, Artificial Embolization

Regulation Number: 882.5950

Product Code: HCG

Device Class: III

C. Predicate Device(s)

Number	Description	Clearance Date
K022420	Micrus Stretch Resistant MicroCoil System	10/22/02
K002056	Micrus MicroCoil Delivery System	01/11/01

D. Device Description

The Micrus Modified MicroCoil System consists of an embolic coil ("MicroCoil") attached to a Device Positioning Unit (DPU) (single use, sterile).

The Micrus Modified MicroCoils are available in a 10-System size, compatible with 10 and 14 sized microcatheters. They are available in helical and spherical shapes and are available in various diameters/lengths:

- Coil lengths range from 1 to 30 centimeters.
- Coil diameters range from 2 to 10 millimeters.

Micrus Modified MicroCoils are fabricated from a platinum alloy wire, which is first wound into a primary coil (containing an absorbable polymer suture inside the wind) and then formed into a secondary helical or spherical shape. The difference between the Micrus Modified MicroCoil and the Micrus Stretch Resistant MicroCoil is that the Modified MicroCoil contains absorbable polyglycolic acid (PGA) suture whereas the Stretch Resistant MicroCoil contains non-absorbable polypropylene suture.

The Modified MicroCoils are available in both stretch resistant and non-stretch resistant configurations with different stiffness levels. The following table illustrates the softness characteristics and stretch resistant properties of the various size/shape combinations available for the Modified MicroCoil.

Modified MicroCoil ("Cerecyte") Shape/Size Combinations and Resulting Characteristics

Catalogue Designation	*Shape*	*Diameter "mm"*	*Length "cm"*	*Stretch Resistant (Yes/No)*	*Characteristics*
Helical Modified Coils					
"CFS"	Helical	2 – 4	1 – 8	Yes	Soft finishing coil • 0.0015" platinum wire
"CHS"	Helical	2 – 10	1 – 30	Yes	Regular filling coil • 0.00175" platinum wire
"CHE"	Helical	2 – 10	1 – 30	No	Regular filling coil • 0.002" platinum wire
Spherical Modified Coils					
"CSS"	Spherical	2 – 4	2.5 – 7.5	Yes	Soft framing coil • 0.00175" platinum wire
"CSP"	Spherical	2 – 10	2.5 – 20.5	No	Regular framing coil • 0.002" platinum wire

The Modified MicroCoils maintain the same design features as the current Micrus MicroCoil Systems. Compared with the current design, Modified MicroCoils have:

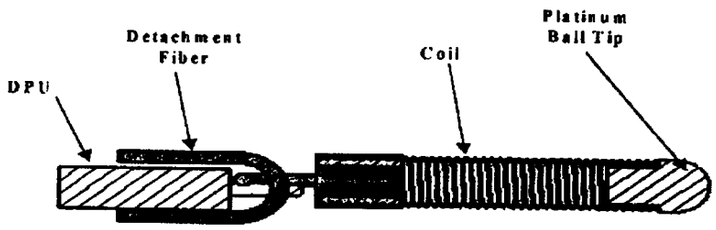
- The same intended use
- Connect to the same connecting cables
- Detach using the same Detachment Control Box.

It is important to reiterate, the Micrus Modified MicroCoils are identical to the current CE Marked / FDA cleared Micrus MicroCoils with the following 2 exceptions:

1. *Non-Stretch Resistant Modified MicroCoils Spacing.* The current non-stretch resistant MicroCoil uses 0.00175" platinum wire wound with a 0.00175" pitch or 0.002" platinum wire wound with a 0.002" pitch. The Modified non-stretch resistant MicroCoil uses 0.002" platinum wire wound with a 0.004" pitch.
2. *Absorbable suture in all Modified MicroCoils:* Biocompatible, absorbable suture has been inserted inside the primary wind of all Modified MicroCoils.

Comparison of Current and Modified Non-Stretch Resistant MicroCoils

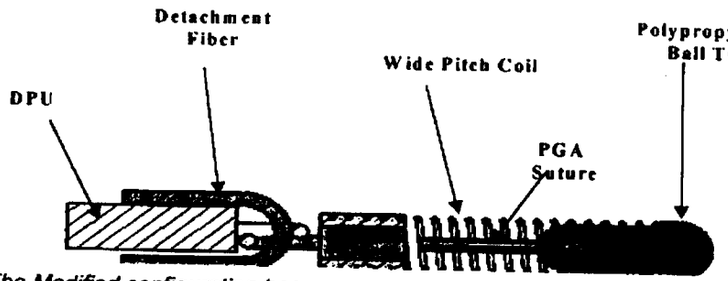
Current Micrus Non-Stretch Resistant MicroCoil



The current, FDA cleared MicroCoil configuration has:

- *platinum ball tip,*
- *no suture, and*
- *0.00175" or 0.002" pitch.*

Modified Non-Stretch Resistant MicroCoil

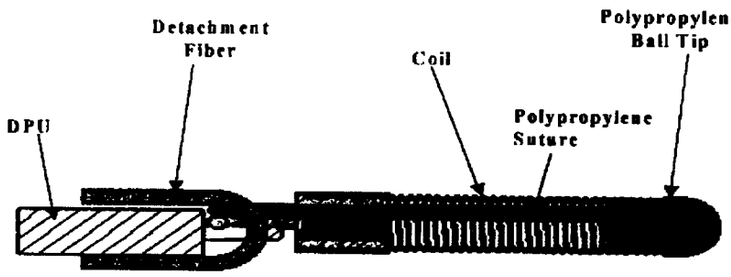


The Modified configuration has:

- *polyethylene ball tip,*
- *PGA suture inside the primary wind (that does not extend to the detachment zone, and*
- *0.004" pitch*

Comparison of Current and Modified Stretch Resistant MicroCoils

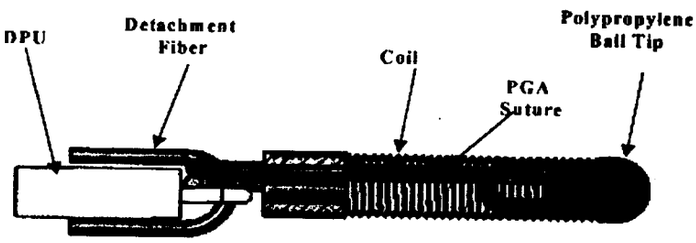
Current Micrus Stretch Resistant MicroCoil



The current configuration has:

- *a polypropylene ball tip,*
- *polypropylene suture that extends to the detachment zone, and*
- *0.00175" or 0.002" pitch.*

Modified Stretch Resistant MicroCoil



The Modified configuration has:

- *a polyethylene ball tip,*
- *PGA suture inside the primary wind that extends to the detachment zone, and*
- *0.0175" or 0.002" pitch.*

E. Intended Use

Intended Use of the Micrus Modified MicroCoil Delivery System per the IFU:

The Micrus MicroCoil Delivery System is intended for endovascular embolization of intracranial aneurysms.

Intended Use of the Predicate Micrus MicroCoil Delivery System per the IFU:

The Micrus MicroCoil Delivery System is intended for endovascular embolization of intracranial aneurysms.

F. *Technological Comparison*

MicroCoil System

Characteristic	Micrus MicroCoil System Predicate	Micrus Stretch Resistant Predicate	Micrus Modified MicroCoil System
How Supplied	Sterile, Single Use	Sterile, Single Use	Same as predicates
	MicroCoil attached to DPU.	Coil attached to pusher wire.	Same as predicates
	Polyethylene introducer over coil.	Polyethylene introducer over coil.	Same as predicates
	In plastic packaging hoop.	In plastic packaging hoop.	Same as predicates

Implantable Embolic Coil

Characteristic	Micrus MicroCoil Predicate	Micrus Stretch Resistant Predicate	Micrus Modified MicroCoil System
Materials of Construction	Platinum/Tungsten alloy wire & Au/Sn solder.	Platinum/Tungsten alloy wire & Au/Sn solder.	Same as predicates
	No suture	Polypropylene suture.	PGA suture
Shape	2 mm – 30 mm	2 mm – 15 mm	2 – 30 cm
Dimensions	Various diameters and lengths to treat a variety of aneurysm sizes.	Various diameters and lengths to treat a variety of aneurysm sizes.	Same as predicates
Radiopacity	Radiopaque from Pt alloy wire.	Radiopaque from Pt alloy wire.	Same as predicates
MRI Compatibility	Yes	Yes	Same as predicates
Method of Attachment to DPU	High tensile strength, highly oriented polyethylene fiber.	High tensile strength, highly oriented polyethylene fiber.	Same as predicates
Method of Detachment from DPU	Shear polyethylene fiber with a loop of resistively heated coil.	Shear polyethylene fiber with a loop of resistively heated coil.	Same as predicates
Provided:	Sterile, single use	Sterile, single use	Same as predicates

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Device Positioning Unit

Characteristic	Micrus MicroCoil Predicate	Micrus Stretch Resistant Predicate	Micrus Modified MicroCoil System
Physical	Variable stiffness. Composite introducer. Most flexible distally, medium flexibility in mid-section and stiffest proximally to allow pushing of the embolic coil through the tortuous cerebral vasculature.	Variable stiffness. Composite introducer. Most flexible distally, medium flexibility in mid-section and stiffest proximally to allow pushing of the embolic coil through the tortuous cerebral vasculature.	Same as predicates Same as predicates Same as predicates
Construction	Stainless steel hypotube (proximal), stainless steel braid (mid) and polymer (distal) sheathing for 2 conduction wires and distal RH coil.	Stainless steel hypotube (proximal), stainless steel braid (mid) and polymer (distal) sheathing for 2 conduction wires and distal RH coil.	Same as predicates
Working Length	195 cm	195 cm	Same as predicates
Package Configuration	In plastic packaging hoop. Introducer in place (for introduction of MicroCoil into the microcatheter). Low density polyethylene & polyester outer package	In plastic packaging hoop. Introducer in place (for introduction of coil into the microcatheter). Low density polyethylene & polyester outer package	Same as predicates Same as predicates Foil pouch with a low density polyethylene coating on inside and polyester coating on outside
Compatible with:	Microcatheters with minimum 0.14" i.d. ("10" sized systems), or 0.16" i.d. ("18" sized systems). 2 radiopaque tip markers 3 cm apart (examples: Tracker 10, Tracker 18, Excel 14, Prowler 10, Prowler 14).	Microcatheters with minimum 0.14" i.d. ("10" sized systems). 2 radiopaque tip markers 3 cm apart (examples: Tracker 10, Tracker 18, Excel 14, Prowler 10, Prowler 14).	Same as predicates "10" sized systems Same as predicates

Connecting Cables (Unchanged for Micrus Modified MicroCoil)

Characteristic	Micrus MicroCoil Predicate	Micrus Stretch Resistant Predicate	Micrus Modified MicroCoil System
How supplied	Sterile, single use	Sterile, single use	Same as predicates
Physical	Single cable with proprietary connectors to fit only the Micrus Detachment Control Box and the Micrus MicroCoil System	Single cable with proprietary connectors to fit only the Micrus Detachment Control Box and the Micrus MicroCoil System	Same as predicates
Length	262 cm.	262 cm.	Same as predicates

Detachment Control Box (Unchanged for Micrus Modified MicroCoil)

Characteristic	Micrus MicroCoil Predicate	Micrus Stretch Resistant Predicate	Micrus Modified MicroCoil System
How supplied	Non-Sterile, reusable. Used outside the sterile field.	Non-Sterile, reusable. Used outside the sterile field.	Same as predicates Same as predicates
Power Source	Alkaline batteries.	Alkaline batteries.	Same as predicates
Displays	Voltage, Current, Low Battery, Fault, Detach Cycle	Voltage, Current, Low Battery, Fault, Detach Cycle	Same as predicates
Detachment Cycle Duration	5 seconds	5 seconds	Same as predicates
Output Voltage	6.5 VDC	6.5 VDC	Same as predicates
Output Current	125 mA nominal, 200 mA max.	125 mA nominal, 200 mA max.	Same as predicates

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Detachment Control Box Continued (Unchanged for Micrus Modified MicroCoil)

Characteristic	Micrus MicroCoil Predicate	Micrus Stretch Resistant Predicate	Micrus Modified MicroCoil System
"Detach" feedback	"Detach Cycle" light goes from illuminated to off. Also, a beep sounds once a second for 5 seconds to provide an audible countdown of the 5 second detachment time. Clinician verifies detachment fluoroscopically per device labeling.	"Detach Cycle" light goes from illuminated to off. Also, a beep sounds once a second for 5 seconds to provide an audible countdown of the 5 second detachment time. Clinician verifies detachment fluoroscopically per device labeling.	Same as predicates
Method to attach Connecting Cable to Detachment Box	Proprietary connector; fits only one-way to assure proper polarity.	Proprietary connector; fits only one-way to assure proper polarity.	Same as predicates
Flow of Current	From positive terminal, through positive lead in connecting cable, through positive conductor of DPU, through resistance heating coil, through negative conductor of DPU, through negative lead in connecting cable, back to negative terminal of detachment control box.	From positive terminal, through positive lead in connecting cable, through positive conductor of DPU, through resistance heating coil, through negative conductor of DPU, through negative lead in connecting cable, back to negative terminal of detachment control box.	Same as predicates

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Accessories

Characteristic	Micrus MicroCoil Predicate	Micrus Stretch Resistant Predicate	Micrus Modified MicroCoil System
Accessory Products Required to Perform the Procedure. * - Not provided as part of the system, chosen based upon physician experience and preference.	Micrus Sterile Connecting Cable	Micrus Sterile Connecting Cable	Same as predicates
	Micrus Detachment Control Box	Micrus Detachment Control Box	Same as predicates
	5-7F Guide Catheter*	5-7F Guide Catheter*	Same as predicates
	Microcatheter (see above)*	Microcatheter (see above)*	Same as predicates
	Guide wire compatible with microcatheter*	Guide wire compatible with microcatheter*	Same as predicates
	Continuous saline/heparin saline flush*	Continuous saline/heparin saline flush*	Same as predicates
	Rotating haemostatic valves*	Rotating haemostatic valves*	Same as predicates
	3-Way stopcock*	3-Way stopcock*	Same as predicates
	1-Way valve*	1-Way valve*	Same as predicates
	IV pole*	IV pole*	Same as predicates
	Femoral Sheath*	Femoral Sheath*	Same as predicates
	Alkaline Batteries*	Alkaline Batteries*	Same as predicates

This technological comparison demonstrates the substantially equivalent technologies used in the Micrus Modified MicroCoil Delivery System as compared with the 2 predicate Micrus MicroCoil Systems: (1) Micrus MicroCoil Delivery System, and (2) the Micrus Stretch Resistant MicroCoil System.

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G. *Discussion of Non-Clinical Tests and Conclusions*

The non-clinical tests performed on the Micrus MicroCoil System were based upon the intended use of the device, the performance of the predicate devices (Micrus MicroCoil Delivery System and the Micrus Stretch Resistant MicroCoil System) and an analysis of the failures of the predicate device (as based upon a review of Micrus MDR reports, which are discussed in Section 5).

The following table outlines the important device characteristics and the non-clinical test data generated:

Test	Micrus Modified MicroCoil System Test Result	Substantial Equivalence
Acute Animal Testing V0327- acute outcome	Characteristic: Aneurysm occlusion and detachment reliability. Test data: Coils detached with the first detachment cycle in > 95% of detachments and ≥90% aneurysm occlusion was obtained in all 5 aneurysms.	Substantially equivalent.
Chronic Animal Testing for Coil Stability & Aneurysm Occlusion V0327-chronic outcome	Characteristic: Positional stability and aneurysm occlusion. Test data: Positional stability and aneurysm occlusion maintained through 6 months of implant. No coil compaction present at 6-month angio. Histology showed chronic biocompatibility per study V0401.	Substantially equivalent.
Coil Stiffness/Softness for Wide Pitch Modified MicroCoils V0396	Characteristic: Stiffness limits for the modified coils manufactured with a looser wind (wide pitch). No change was made that would affect the stiffness of the tightly wound coils. Test data: The loosely wound (wide pitch) Helical and Spherical Modified MicroCoils met the stiffness specifications.	Substantially equivalent.
Friction in the Microcatheter (Delivery Force) V0429	Characteristic: Average push force must be substantially equivalent to predicates. Test data: The Modified MicroCoil had average push forces that are comparable to those of the predicate.	Substantially equivalent.
Biocompatibility of Materials V0401 & V0435	Characteristics: Meets the requirements of ISO 10993. Test data: The only new material in the Micrus Modified MicroCoil is absorbable suture, which passed ISO 10993 biocompatibility testing.	Meets ISO 10993

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Sterilization Validation V0394	Characteristic: Minimum Sterility Assurance Level of 10^{-6}. Test data: Passed minimum sterility assurance level of 10^{-6}.	Substantially equivalent.
Shelf Life Test V0397	Characteristic: No performance degradation after 3 year of shelf life aging. Test data: Minimum tensile strength after 3 year accelerated aging shows no degradation.	Substantially equivalent
Tensile Strength: Stretch Resistant Modified MicroCoils (at the detachment zone, PGA to polypropylene junction and suture ball tip to MicroCoil) V0427	Characteristic: Pre-detachment tensile strength of the suture ball tip and MicroCoil to DPU must be substantially equivalent to the stretch resistant predicate. Test data: Tensile strength meets desired strength criteria.	Substantially equivalent to the stretch resistant predicate
Tensile Strength: Non-Stretch Resistant Modified MicroCoils (at the detachment zone) V0398	Characteristic: Pre-detachment tensile strength of the MicroCoil to DPU must be substantially equivalent to the non-stretch resistant predicate. Test data: Tensile strength meets desired strength criteria.	Substantially equivalent to the non-stretch resistant predicate
Tensile Strength: Non-Stretch Resistant (at the suture ball tip) V0428	Characteristic: Pre-detachment tensile strength of the suture ball tip and MicroCoil must be substantially equivalent to the non-stretch resistant predicate. Test data: Tensile strength meets desired strength criteria.	Substantially equivalent to the non-stretch resistant predicate
Durability (Reliability after Fatigue) V0405	Characteristic: Withstand deployment and retraction 6 times in a tortuous anatomy. Test data: No knotting, no breakage, no stretching occurred. Durability meets desired durability criteria.	Substantially equivalent
MRI Compatibility of Implant	No change was made which would impact MRI compatibility.	Substantially equivalent

Package Integrity V0399	Characteristic: Demonstrate package integrity per ISO 11607 Test: Meets ISO 11607 criteria	Meets ISO 11607 criteria
Ship/Transit V0400	Characteristic: Successfully withstand domestic and international distribution environment Test: Does successfully withstand domestic and international distribution environment.	Substantially equivalent

This non-clinical testing has demonstrated the substantially equivalent performance of the Micrus Modified MicroCoil System with the 2 predicate devices: (1) Micrus MicroCoil Delivery System, and (2) Micrus Stretch Resistant MicroCoil System.

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H. Summary of Safety and Effectiveness

Based upon the design, materials, function, intended use, comparison with currently marketed devices and the non-clinical testing performed by Micrus Corporation, it is concluded that the Micrus Modified MicroCoil System is substantially equivalent to the Micrus Stretch Resistant and the Micrus MicroCoil Delivery System in safety and effectiveness.

Margaret Webber

Director, Regulatory and Clinical Affairs

Micrus Corporation

December 5, 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 4 2004

Ms. Margaret Webber
Director, Regulatory and Clinical Affairs
Micrus Corporation
610 Palomar Avenue
Sunnyvale, California 94085

Re: K033813
Trade/Device Name: Micrus Modified Microcoil System, Cerecyte
Regulation Number: 21 CFR 882.5950
Regulation Name: Artificial Embolization Device
Regulatory Class: III
Product Code: HCG
Dated: December 5, 2003
Received: December 9, 2003

Dear Ms. Webber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K033813

Indications for Use

510(k) Number (if known):	K033813
Device Name:	Micrus Modified Microcoil System, Cerecyte
Indications For Use:	The Micrus MicroCoil Delivery System is intended for endovascular embolization of intracranial aneurysms.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033813